REMARKS

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

Status of the Claims

Claims 1-24 are currently pending in the present application. Claims 1, 3, 4 and 5 have been amended to further clarify and define the invention. Support for the amended claims can be found on pages 2, 9-10 and pages 82-84, of the present specification.

Based upon the above considerations, entry of the present Amendment is respectfully requested.

Issue Under 35 U.S.C. § 102(e), Anticipation

Claims 1-2, 7-12 and 15 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent Application Publication No. 2005/0181052 (hereinafter "'052"). Applicants respectfully traverse this rejection.

Although Applicants disagree, in order to advance prosecution, claim 1 has been amended to further define and clarify the claimed invention as it relates to the properties and components of a capsule shell, not the medicine itself since the medicine is unstable to moisture.

The capsule disclosed in the '052 reference is limited to a gelatin capsule (*See* the '052 reference at paragraph 0063). The Examples of the '052 reference disclose only the use of hard

gelatin capsules (*See* paragraph 0069 of the '052 reference). Further, the '052 reference merely discloses a gelatin capsule as a capsule shell, as well as only disclosing the use of hard gelatin capsules in Examples 1 and 2.

Applicants point out that the capsule preparation of the present invention does not use a hard gelatin capsule.

As discussed in the Background Art section of the present specification (*See* pages 1-3), in the case of a capsule preparation which is common in the prior art containing a compound unstable to water such as a benzimidazole type compound, there is a problem that a commonly used hard gelatin capsule has weak mechanical strength in a low moisture state and is apt to be broken.

On the other hand, in a preparation containing a compound unstable to water, typically, a benzimidazole type compound, it is desired to lower the moisture content of the preparation *per se* to improve stability. Then, a capsule into which such a preparation is filled should have good mechanical strength even at a low moisture state.

Under these circumstances, the presently claimed invention provides "a capsule preparation, which comprises a capsule shell and contained inside the capsule shell a medicine unstable to moisture, wherein the capsule shell is stable in a low moisture state and has pH-independent disintegration properties, and provided that the capsule shell excludes hard gelatin and/or a cellulose derivative as a main component of the capsule shell" (claim 1). Therefore, it is clear that the above hard gelatin capsule, or a HPMC capsule which has a problem that solubility is low at low pH (see the Background Art section of the present specification), is excluded from the present invention.

The Examiner has previously stated:

"The composition (a capsule preparation) taught by '052 is stable in a low moisture state. This argument is supported by the wet granulation step." (page 4, middle of the 1st paragraph of the Official Action dated February 7, 2008).

However, Applicants submit that the disclosure in the '052 reference pointed out by the Examiner is directed to the production of granules to be filled in the capsule. The '052 reference does not teach or suggest any solution to such a problem of a hard gelatin capsule, in that a hard gelatin capsule has weak mechanical strength in a low moisture state and is apt to be broken.

As seen from Experiment Example 1 (*See* the present specification at pages 83-84), the fracture ratio of gelatin capsules is very high. Thus, it is clear that a hard gelatin capsule is excluded from the present invention.

Since the '052 reference is silent regarding a capsule shell which is stable in a low moisture state, has pH-independent disintegration properties, and that the capsule shell excludes hard gelatin and/or a cellulose derivative as a main component of the capsule shell, it does not teach the present invention.

Because "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference," the cited '052 reference cannot be a basis for a rejection under § 102. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See MPEP 2131 – To Anticipate a Claim, the Reference Must Teach Every Element of the Claim.

Therefore, Applicants respectfully submit that based on the above, the '052 references does not anticipate the present invention.

Applicants request reconsideration and withdrawal of the present rejection.

Issues Under 35 U.S.C. § 103(a), Obviousness

The following 35 U.S.C. § 103(a) rejections were presented by the Examiner.

Claims 4 and 16-24 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the '052 reference.

Claim 5 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the '052 reference, in view of U.S. Patent No. 5,665,348 (hereinafter "'348").

Applicants respectfully traverse the above rejections.

Although Applicants disagree with the Examiner's assertions, in order to advance prosecution, claims 4 and 5 have been amended, to further define and clarify the claimed invention as it relates to the properties and components of the claimed capsule shell.

Graham v. John Deere, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), has provided the controlling framework for an obviousness analysis. A proper analysis under 35 U.S.C. § 103(a) requires consideration of the four *Graham* factors of: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary considerations (*e.g.*, commercial success; unexpected results). 383 U.S. at 17, 148 USPQ at 467.

M.P.E.P. § 2143 sets forth the guidelines in determining obviousness. But before the Examiner can utilize these guidelines, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*; *supra*. To reject a claim based on the above mentioned guidelines, the Examiner must resolve the *Graham* factual inquiries. MPEP §2143. If the Examiner resolves the *Graham* factual inquiries, then the Examiner has to provide some rationale for determining obviousness, wherein M.P.E.P. § 2143 sets forth the rationales that were established in *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Applicants respectfully submit that the Examiner has not appropriately resolved the *Graham* factors, including the factors of determining the scope and content of the prior art and ascertaining the differences between the prior art and the claims that are at issue. Based on the following, Applicants maintain that the above-mentioned *Graham* factors actually work in Applicants' favor. Additionally, Applicants submit that since the Examiner did not resolve the *Graham* factors, the rationales the Examiner provides for the above rejections are improper.

Applicants respectfully submit that the presently claimed invention is unobvious over the cited references in the presented rejections, for the following reasons.

Differences between the invention and the prior art

Applicants herein incorporate the above comments concerning the differences between the presently claimed invention and the '052 reference.

Additionally, a further difference to note is that the presently amended claims refer to the

components of the capsule shell itself. In this respect, the Examiner has mistakenly confused components of the capsule itself with components, *i.e.*, the contents of the capsule.

More specifically, regarding claim 4, the Examiner previously stated that:

"...The capsule preparation disclosed by '052 further comprises a lubricant, optionally one or more excipients, and an enteric coating, wherein the weight ratio of lansoprazole to lubricant is from about 1:4 to about 8:1, respectively. Preferred, not-limiting, examples of excipients include microcrystalline cellulose, maltodextrin, starch, and various cellulose derivatives. All of the above excipients are polysaccharides." (see page 7, the 1st paragraph of the Official Action dated February 7, 2008).

However, Applicants submit that the polysaccharide claimed in amended claim 4 defines the main component of the capsule shell, not the contents to be filled in the capsule. As mentioned above, '052 reference do not teach or suggest the capsule shell preparation of the present invention.

Applicants respectfully disagree with the Examiner that the present invention would be obvious to the skilled artisan. In view of the above, it submitted that the present invention as claimed is distinguished over the '052 reference.

In light of the above presently amended claims and remarks, because there is no disclosure, teaching, suggestion, reason or rationale provided in the cited references that would lead one of ordinary skill in the art to arrive at the instant invention as claimed, it follows that the '052 reference is incapable of rendering the instant invention obvious under the provisions of 35 USC § 103(a). Based upon the above, and applying the *Graham factors* analysis test, it is submitted that a *prima*

facie case of obviousness has not been established.

Regarding the rejection of claim 5, the presently claimed invention is distinguished from the '052 reference for the reasons discussed above. The Examiner further cited the '348 reference. Applicants point out that this reference discloses pullulan as a component of the contents to be filled in a capsule, *i.e.*, an excipient of a pharmaceutical composition itself, not a capsule shell component. There is no teaching or suggestion of a pullulan capsule shell in this reference. Applicants submit that even if the '348 reference is combined with '052 reference, they do not teach or suggest the presently claimed invention. Therefore, the '348 reference fails to cure the deficiencies of the '052 reference.

Applicant respectfully requests reconsideration and withdrawal of the present rejections.

CONCLUSION

Applicants respectfully submit that all of the rejections raised by the Examiner have been overcome, and that the present application now stands in condition for allowance.

Should there be any outstanding matters that need to be resolved, the Examiner is respectfully requested to contact Paul D. Pyla at the telephone number below, in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized to charge payment or credit any overpayment to Deposit Account No. 23-0975 for any additional fees required under 37.C.F.R. §§1.16 or 1.17.

Respectfully submitted,

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